DEPARTMENT OF HEALTH AND HUMAN SERVICES

95083d
Public Health Service
Food and Drug Administration
Central Region

New Jersey District
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6009

November 19, 2004

WARNING LETTER

CERTIFIED MAIL-
RETURN RECEIPT REQUESTED

David Holmes
President
Pharmachem Laboratories, Inc.
265 Harrison Avenue
Kearny, New Jersey 07032-4315

File No.: 05-NWJ-02

Dear Mr. Holmes:

On August 4, 6, and 11, 2004, an investigator from the Food and Drug Administration's (FDA) New Jersey District Office visited your manufacturing facility and corporate office located at 265 Harrison Avenue, Kearny, New Jersey 07032. During this inspection, our investigator was provided promotional materials for Phase 2® Starch Neutralizer [Phaseolamin® 2250], a bulk dietary ingredient manufactured by your firm and sold to other firms for use in the manufacture of dietary supplement products.

We have reviewed this information, including the "clinical study" abstracts and articles referred by you and located on your websites at http://www.pharmachem.com and http://www.phase2info.com, and find that your Phase 2® Starch Neutralizer product violates the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321 *et seq.*). Specifically, we have determined that your Phase 2® Starch Neutralizer product is misbranded under section 403(a)(1) of the Act (21 U.S.C. § 343(a)(1)) because claims in this product's labeling, which includes promotional materials under section 201(m) of the Act (21 U.S.C. § 321(m)), are false or misleading. You can find the Act and FDA's food labeling regulations through links on FDA's Internet home page at http://www.fda.gov.

As stated in section 201(ff) of the Act (21 U.S.C. § 321(ff)), a dietary supplement is a food within the meaning of the Act (unless it meets the definition of a drug). A food is defined in the Act to include articles used for components of food (21 U.S.C. § 321(f)). Because your Phase 2® Starch Neutralizer product is a dietary ingredient used in and as a component of dietary supplements, your product is considered a food under the Act. Accordingly, your product must comply with the Act, including applicable food labeling provisions.

Your Phase 2® Starch Neutralizer product labeling, including your promotional literature and websites, includes the following claims:

- "Phase 2® . . . 'neutralizes' the digestive enzyme alpha amylase before it can convert starch into glucose and then fat. Essentially, it allows the carbohydrates to pass through the system possibly with less caloric intake."
- "...new, standardized extract, Phase-2™, has been successfully clinically studied to 'neutralize' dietary starch absorption by over 70%, with slow, steady stimulant-free weight loss."
- "Several clinical studies of Phase 2 Starch Neutralizer™ have demonstrated efficacy in weightloss [sic] and in the improvement of post-prandial glucose tolerance."
- "...has been clinically & scientifically proven to neutralize starch ...."
- "Phase 2® is a safe yet powerful nutritional ingredient, clinically studied to reduce the absorption of starch calories."
- "Phase 2® allows you to enjoy those foods that you love without all the calories."

We have reviewed these claims as well as the studies located on your website and have concluded that these claims are not supported by competent and reliable scientific evidence. Because these claims lack substantiation, they are false or misleading, and cause your product to be misbranded within the meaning of section 403(a)(1) of the Act. It is a violation of section 301(a) of the Act (21 U.S.C. 331(a)) to introduce or deliver for introduction into interstate commerce any food, including a dietary ingredient, that is misbranded. It is a violation of section 301(k) of the Act (21 U.S.C. § 331(k)) to commit any act with respect to a food if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being misbranded.

This letter is not intended to be an all-inclusive review of the labeling, including promotional literature or your websites, for products marketed by your firm. You should take prompt action to correct any violations identified in this letter. Failure to do so may result in enforcement action, such as seizure or injunction, without further notice.

Please advise this office, in writing and within fifteen (15) working days of receipt of this letter, as to the specific steps that you have taken to correct any violations and to assure that similar violations do not occur. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be made.

Your written response should be addressed to the attention of Mercedes Mota, Compliance Officer, FDA, New Jersey District Office, 10 Waterview Bldg., 3rd Floor, Parsippany, New Jersey 07054.

Sincerely,

Douglas I. Ellsworth

Douglas I. Ellsworth
District Director
New Jersey District